



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,127	04/16/2004	Naoyuki Fukuchi	251865US0CONT	7991
22850 7590 03/23/2007 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER GABEL, GAILENE	
			ART UNIT	PAPER NUMBER
			1641	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		03/23/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/23/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No. 10/825,127	Applicant(s) FUKUCHI ET AL.	
	Examiner Gailene R. Gabel	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-35 is/are pending in the application.
- 4a) Of the above claim(s) 21-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 21-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/16/04; 11/9/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group III, claims 31-35, with traverse, filed January 12, 2007 is acknowledged and has been entered. Claims 21-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Accordingly, claims 21-35 are pending. Claims 31-35 are under examination.

2. Applicant traverses the restriction requirement on the grounds that the Office has not shown that a burden exists in searching the entire application. Applicant contends that the search of all the claims would not impose serious burden on the Office.

Applicant's argument is not persuasive because the different groups are distinct in that the structural requirements for each invention are different, hence each requiring different searches and separate examinations for novelty or obviousness and patentability determination. Therefore, while searches would be expected to overlap, there is no reason to expect the searches and examinations for each group to be coextensive. Accordingly, the restriction requirement is being maintained.

Priority

Art Unit: 1641

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/673,245, filed on October 23, 2000.

Specification

4. The reference to the prior applications inserted in the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), 35 U.S.C. 119(e), 120, 121, or 365(c), 37 CFR 1.78(a), does not include the status (i.e. US Patent Number or Abandoned) of all nonprovisional applications (i.e., continuation, divisional, or continuation-in-part). Please update the status of all nonprovisional applications.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 31-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 is indefinite and confusing in reciting, "A chimeric protein, which consists of an Fc region ... fused at its amino terminus to a partial protein comprising..." because the scope of what consists of the claimed chimeric protein is not determinable. Specifically, the transition language "which consists of" is a closed language which

Art Unit: 1641

intends limiting the scope of elements that is encompassed within the chimeric protein. However, by proceeding to reciting, "partial protein comprising", the scope of the recited partial protein is left open so as to render the scope of the claimed chimeric protein indeterminable.

Same analogous comment or problem applies to claim 35.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruggeri et al. (WO 93/16712) in view of Simonet et al. (US 6,790,823).

Ruggeri et al. disclose antithrombotic polypeptides based upon partial proteins (fragments) of glycoprotein Iba (GPIba). The polypeptides are modified and patterned on fragments of GPIba that comprise all or part of the binding domain of GPIba for von Willebrand Factor (vWF). Ruggeri et al. specifically provide that the actual binding site for vWF on GPIb-IX receptor is localized on the region of GPIba chain comprising amino acid 1-293 residues of the GPIba chain. See page 9, lines 3-24; page 12, lines 24-31; page 13, lines 15-39; and page 16, lines 15-19.

Art Unit: 1641

Ruggeri et al. differs from the instant invention in failing to teach fusing the partial protein to an Fc region of immunoglobulin molecule fused at its amino terminus.

Simonet et al. disclose a chimeric protein comprising a fusion of a polypeptide with an Fc region of human immunoglobulin G (IgG). Simonet et al. specifically teaches that fusion to the Fc region may occur between the amino terminus of an Fc region and the carboxy terminus of the polypeptide. See column 5, lines 50-62 and column 4, lines 25-50.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate an Fc region of human IgG in the amino terminus of the Fc region as taught by Simonet into the vWF binding site of the GPIIb α chain which comprises a partial protein as taught by Ruggeri to form a chimeric protein because Simonet suggested fusion of an Fc region of human IgG into a modified polypeptide such as that taught by Ruggeri which comprises of a modified polypeptide in the form of a partial protein which comprises of the vWF binding site of the GPIIb α chain. Additionally, generation of chimeric or fusion proteins by virtue of fusion of protein fragments with specific Ig fragments appears to be conventional and well-known practice in pharmaceutical medicine for treatment of different types of diseases.

NOTE: Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Art Unit: 1641

7. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruggeri et al. (WO 93/16712) in view of Simonet et al. (US 6,790,823) and in further view of Foster et al. (US Patent 4,444,879).

Ruggeri et al. and Simonet et al. are discussed supra. Ruggeri et al. and Simonet et al. differ from the instant invention in failing to teach incorporating the vWF and the chimeric protein into a kit format.

Foster et al. teach incorporating reagents, antibodies, antigens, and labels into a kit format. See column 15.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the vWF and chimeric protein taught by Ruggeri as modified by Simonet into a kit arrangement as taught by Foster because test kits are conventional and well known in the art for their recognized advantages of convenience and economy.

NOTE: Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.\

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571)

Art Unit: 1641

272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
March 15, 2007

